VINEGAR

September 10, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Via Fax: 301/827 - 6870

RE: Food; Current Good Manufacturing Practice Regulations; Public Meetings
[Docket No. 2004N-0230]

Dear Sir or Madam:

The Vinegar Institute (VI) is an international trade association representing manufacturers and bottlers of vinegar and suppliers to this industry. VI submits the following comments on the Food and Drug Administration's (FDA) May 21, 2004 *Federal Register* (69 FR 29220) notice regarding review and modernization of the current good manufacturing practice (CGMP) regulations for food as defined in 21 Code of Federal Regulations (CFR) part 110.

The CGMPs include provisions regarding food industry personnel; plants and grounds; sanitary facilities, controls and operations; equipment and utensils, warehousing, and distribution; and natural or unavoidable defect levels. These regulations help to ensure the safe and sanitary manufacturing, processing and holding of food for humans. VI looks forward to reviewing specific details regarding the Agency's review of the CGMP regulations and proposed revisions. During this process, VI believes the Agency should ensure the regulations remain flexible and broad and the economic impact of any proposed changes should be considered. Our detailed comments follow.

VI believes the CGMPs must provide flexibility to accommodate the variations that exist in food manufacturing. Food manufacturing facilities in the U.S. produce a variety of food products utilizing a myriad of processes. These facilities also differ in size with varying levels of resources available to them. New technologies and processes are continually being developed to ensure a safe food supply, and specifying methods would limit the food industry's ability to quickly adopt any emerging technologies. As such, the CGMP regulations should remain broad in scope and provide a general foundation for the manufacture of safe foods.

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We encourage the FDA to consider the economic impact to large and small food manufacturers of any revisions to the CGMP regulations. If the Agency mandates certain training, recordkeeping, testing or audit programs as part of these regulations, manufacturers will bear the associated costs. Such costs should be closely weighed against the public health benefits.

VI appreciates your consideration of these comments. We look forward to providing additional industry comments as details are provided by the Agency.

Sincerely,

Patricia Faison

Patricia Faison, M.S.
Technical Manager

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